

Clinical trials of direct antithrombins for atrial fibrillation in all type of patients

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1 oral direct thrombin inhibitor

| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|--|
| dabigatran 110mg vs warfarin standard dose | | | |
| RE-LY (110mg) , 2009 [NCT00262600] n=6015/6022 follow-up: 2 y (median) | dabigatran 110 mg twice a day versus warfarin adjusted dose to a 2-3 INR | Patients With Non-Valvular Atrial Fibrillation | Parallel groups open (blind assessment) 44 countries |
| dabigatran 150mg vs warfarin standard dose | | | |
| PETRO (150mg) , 2007 n=166/70 follow-up: 12 weeks | dabigatran 150 mg twice daily (alone or combined with 81- or 325-mg aspirin) versus warfarin administered to achieve an international normalized ratio of 2 to 3 for | patients with AF at high risk for thromboembolic events | Factorial plan double blind Denmark, The netherlands, Sweden, US |
| RE-LY (150mg) , 2009 [NCT00262600] n=6076/6022 follow-up: 2 y (median) | dabigatran 150 mg twice a day versus warfarin adjusted-dose to a 2.0 to 3.0 INR | Patients With Non-Valvular Atrial Fibrillation | Parallel groups open (blind assessment) 44 countries |
| ximelagatran vs warfarin standard dose | | | |
| SPORTIF V , 2005 n=1960/1962 follow-up: 20 months | ximelegatran 36 mg twice daily versus warfarin standard dose(target INR 2-3) | One or more stroke risk factor in addition to atrial fibrillation.High risk patients with non valvular atrial fibrillation. | Parallel groups Double blind north america |
| SPORTIF II (ximelagatran vs warfarin standard dose) , 2002 n=187/67 follow-up: 16 weeks | ximelegatran 20,40,60 mg twice daily versus warfarin standard dose(target INR 2-3) | Medium to high risk patients with chronic non valvular atrial fibrillation. | Parallel groups Open Europe ,USA |
| SPORTIF III , 2003 n=1704/1703 follow-up: 17.4 months | ximelagatran 36 mg twice daily versus warfarin standard dose (target INR 2-3) | One or more stroke risk factor in addition to AF.High risk patients with non valvular atrial fibrillation. | Parallel groups Open europe,asia,australasia |

References

RE-LY (110mg), 2009:

PETRO (150mg), 2007:

RE-LY (150mg), 2009:

SPORTIF V, 2005:

SPORTIF II (ximelagatran vs warfarin standard dose), 2002:

2 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.